

PATENT COOPERATION TREATY

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JUN 29 2009

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

BY: *qm*

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

To:

HISCOCK & BARCLAY, LLP
Attn. Womer, Jason R.
2000 HSBC Plaza
100 Chestnut Street
Rochester, NY 14604-2404
ETATS-UNIS D'AMERIQUE

(PCT Rule 44.1)

Date of mailing
(day/month/year)

29/06/2009

Applicant's or agent's file reference

3009040 WO02

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/US2008/050375

International filing date
(day/month/year)

07/01/2008

Applicant

FXS VENTURES, LLC

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Andrea Oberhauser

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1bis(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43bis.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 3009040 WO02	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2008/050375	international filing date (day/month/year) 07/01/2008	(Earliest) Priority Date (day/month/year) 05/01/2007
Applicant FXS VENTURES, LLC		

This international search report has been prepared by this international Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the international Bureau.

This international search report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. _____
☐ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention
b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/050375

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61L12/14 C11D3/00 C11D3/32 C11D3/33 C11D3/34
C11D3/37

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61L C11D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/148665 A1 (SMITH FRANCIS X [US]) 6 July 2006 (2006-07-06)	1-14
Y	page 1, paragraphs 6,7 page 1, paragraph 12 - page 2, paragraph 19 claims 1-7	1-14
X	WO 02/062260 A (BIO CONCEPT LAB [US]; SMITH FRANCIS XAVIER [US]) 15 August 2002 (2002-08-15)	1-14
Y	claims 1-7 page 3 - page 6	1-14
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☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

15 June 2009

Date of mailing of the international search report

29/06/2009

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Romano-Götsch, R

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/050375

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 93/04706 A (ALLERGAN INC [US]) 18 March 1993 (1993-03-18) page 6, lines 7-30 page 10, line 16 - page 11, line 35 examples 1-3 claims 7,19	12,13
X	US 2003/190258 A1 (SMITH FRANCIS X [US]) 9 October 2003 (2003-10-09) page 5 - page 6; examples 8-10	12,13
X	JP 2006 089403 A (FUJITA HIRONORI; SENJU PHARMA CO) 6 April 2006 (2006-04-06)	12,13
Y	see also English automatic translation from JPO website: http://dossier1.ipdl.inpit.go.jp paragraphs [0040] - [0042]; examples 7,8	1-14
X	JP 08 152584 A (ASAHI CHEMICAL IND) 11 June 1996 (1996-06-11) abstract	12,13
X	WO 02/38161 A (BIO CONCEPT LAB [US]; SMITH FRANCIS XAVIER [US]) 16 May 2002 (2002-05-16) page 1 - page 2; claims	12,13
Y	GB 1 431 841 A (EVANS S C) 14 April 1976 (1976-04-14) page 2, lines 30-76; claim 1	12,13
P,X	US 2007/104744 A1 (SMITH FRANCIS X [US]) 10 May 2007 (2007-05-10) page 1, paragraph 13 - page 2, paragraph 21 claims 1-12	1-14
E	WO 2008/077110 A (FXS VENTURES LLC [US]; SMITH FRANCIS X [US]) 26 June 2008 (2008-06-26) page 2, paragraphs 6,7 page 4, paragraph 15-19 claims 1-14	1-14

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/050375

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006148665	A1	06-07-2006	NONE
WO 02062260	A	15-08-2002	AT 406167 T 15-09-2008
			AT 405265 T 15-09-2008
		AU 2595002 A 21-05-2002	
		AU 3954502 A 27-05-2002	
		AU 2002225950 B2 10-08-2006	
		AU 2002239545 B2 05-10-2006	
		AU 2002251685 B2 27-10-2005	
		CA 2428994 A1 15-08-2002	
		CA 2428997 A1 23-05-2002	
		CA 2434961 A1 16-05-2002	
		CN 1486186 A 31-03-2004	
		CN 1505520 A 16-06-2004	
		CN 1486187 A 31-03-2004	
		DK 1337262 T3 15-12-2008	
		DK 1331902 T3 08-12-2008	
		EP 1337262 A2 27-08-2003	
		EP 1339414 A2 03-09-2003	
		EP 1331902 A2 06-08-2003	
		EP 1992340 A1 19-11-2008	
		ES 2311555 T3 16-02-2009	
		ES 2311035 T3 01-02-2009	
		JP 2004512901 T 30-04-2004	
		JP 2004525865 T 26-08-2004	
		JP 2004526186 T 26-08-2004	
		PT 1337262 E 24-10-2008	
		PT 1331902 E 02-12-2008	
		WO 0238077 A2 16-05-2002	
		WO 0240062 A2 23-05-2002	
WO 9304706	A	18-03-1993	AT 156367 T 15-08-1997
		AU 653432 B2 29-09-1994	
		AU 2557392 A 05-04-1993	
		CA 2095022 A1 01-03-1993	
		DE 69221463 D1 11-09-1997	
		DE 69221463 T2 05-03-1998	
		DE 555464 T1 15-02-1996	
		DK 555464 T3 09-02-1998	
		EP 0555464 A1 18-08-1993	
		ES 2106882 T3 16-11-1997	
		FI 931940 A 29-04-1993	
		GR 3024488 T3 28-11-1997	
		HU 64240 A2 28-12-1993	
		IL 102905 A 14-11-1996	
		JP 6501643 T 24-02-1994	
		JP 3234600 B2 04-12-2001	
		JP 3904851 B2 11-04-2007	
		JP 2002082055 A 22-03-2002	
		KR 100256116 B1 01-06-2000	
		MX 9204912 A1 01-02-1993	
		NO 931571 A 29-04-1993	
		NZ 243749 A 25-11-1994	
		PL 299186 A1 27-12-1993	
		PL 172353 B1 30-09-1997	
		PT 100825 A 28-02-1994	
		RU 2114638 C1 10-07-1998	
		US 5578240 A 26-11-1996	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/050375

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9304706	A	ZA 9206522 A	28-04-1993
US 2003190258	A1	09-10-2003	NONE
JP 2006089403	A	06-04-2006	NONE
JP 8152584	A	11-06-1996	JP 3442168 B2 02-09-2003
WO 0238161	A	16-05-2002	AU 2720602 A 21-05-2002
		AU 2002227206 B2	21-09-2006
		CA 2428985 A1	16-05-2002
		CN 1486188 A	31-03-2004
		EP 1339418 A1	03-09-2003
		JP 4084997 B2	30-04-2008
		JP 2004512904 T	30-04-2004
GB 1431841	A	14-04-1976	NONE
US 2007104744	A1	10-05-2007	WO 2008086270 A2 17-07-2008
WO 2008077110	A	26-06-2008	US 2007098818 A1 03-05-2007

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2008/050375

International filing date (day/month/year)
07.01.2008

Priority date (day/month/year)
05.01.2007

International Patent Classification (IPC) or both national classification and IPC
INV. A61L12/14 C11D3/00 C11D3/32 C11D3/33 C11D3/34 C11D3/37

Applicant
FXS VENTURES, LLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

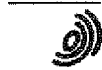
If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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D-80298 Munich
Tel. +49 89 2399 - 0
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Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Romano-Götsch, R

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2008/050375

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2008/050375

Box No. II Priority

1. ☐ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☒ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

see separate sheet

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	<u>1-14</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-14</u>
Industrial applicability (IA)	Yes: Claims	<u>1-14</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)
and /or
2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

see form 210

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2008/050375

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item II.

For a valid claim to priority, the application the priority of whose filing date is claimed must be the first application that has been filed for the invention. A subsequent application for the same subject-matter as the previous application filed for the same State is considered as the first application for priority purposes if, when this subsequent application is filed, the first application had been withdrawn, abandoned or refused without being open to public inspection or without leaving any rights outstanding, and has not served as basis for claiming priority (Art. 8(1)PCT; Rule 4.10 PCT).

In the present case, at the date of filing US 2007/104744 A1 (D9) (which is claimed as priority by the present application), the application corresponding to US 2006/148665 A1 (D1) has not been withdrawn, abandoned or refused.

It follows that present subject-matter of claims 1-14 (namely claims 1-11, part of claims 12-13, and claim 14) that has been already disclosed in document D1 is not entitled to the claimed priority. For said subject-matter, D1 and D9 form prior art according to Art.33 (2) and Rule 33.1 PCT.

The additional subject-matter disclosed in claims 12-13 is rightly claims D9 as priority document.

Re Item V.

Reference is made to the following documents:

- D1: US 2006/148665 A1
- D2: WO 02/062260 A
- D3: WO 93/04706 A
- D4: US 2003/190258 A1
- D5: JP 2006 089403 A
- D6: JP 08 152584 A
- D7: WO 02/38161 A
- D8: GB 1 431 841 A
- D9: US 2007/104744 A1 (2007-05-10)

The presently claimed matter 1-14 lacks novelty in the sense of Art.33(2) PCT, as being anticipated by the following documents:

Documents D1 (claims 1-7), **D2** (claims 1-7) and **D9** (par.6-7) disclose a contact lenses solution comprising **0.001%** of a preservative enhancer chosen from the group consisting of thiamine (B1), riboflavin (B2), niacin (B3), pantothenic acid (B5), pyridoxine (B6), and cobalamin (B12); and at least 0.0001 weight percent of a cationic polymeric preservative and a concentration of 0.2 or less percent chloride, and the

same additives claimed in the application.

D1 (par.12-14) and D2 (pp.3-4) further disclose contact lens solutions comprising 0.0001% to about 1.0% of one of the vitamin B forms chosen from the group consisting of thiamine (B1), riboflavin (B2), niacin (B3), **panthenol** (B5), pyridoxine (B6), and cobalamin (B12), **folic acid, carnitine, inositol**.

It follows that D1, D2 and D9 are novelty destroying for claims 1-14.

The following documents anticipate the novelty of claims 12-13.

Document D3 (see passages cited in the search report) discloses a contact lens solution comprising vitamin B12 in the form of cyanocobalamin or cobalamin or derivatives such as methyl-, hydroxy- or desoxyadenoxsyl-cobalamin.

Document D4 (see in particular examples 8-10) discloses several solutions for storing, rinsing and disinfecting contact lenses comprising inositol and choline. Thus, D4 anticipates the novelty of claims 12-13.

Document D5 discloses (examples 7-8) eye drops for contact lens removal comprising pyridoxine hydrochloride.

Document D6 discloses a contact lens solution comprising one or more compounds selected from pyridoxine hydrochloride, cyanocobalamin, flavine adenine dinucleotide sodium(FAD).

Document D7 discloses (p.2) a contact lens solution comprising inositol.

In view of the outstanding novelty objections, an inventive step cannot be acknowledged for claims 1-14 (Art.33 (3) PCT).

Re Item VI

WO2008/077110 A published on 26.06.2008, with an international filing date of 19.12.2007 and claiming a priority date of 19.12.2006.

Re Item VII

The expression "Vitamin B Complex" does not have a defined meaning and renders the scope of claims 12 and 13 unclear (Art. 6 PCT).

Claim 13 contains several repetitions: some names are repeated more than once (e.g. thiamine, folic acid); furthermore the vitamins as well as the corresponding compounds (e.g. vitamin B-1 is thiamin, vitamin B-2 is riboflavin) are recited in the claim.

Consequently, claim 13 is unclear and lacks of conciseness.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	<p>For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.</p>
Amending claims under Art. 19 PCT	<p>Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.</p>
Filing a demand for international preliminary examination	<p>In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).</p> <p>If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).</p>
Filing informal comments	<p>After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.</p>
End of the international phase	<p>At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).</p>
Relevant PCT Rules and more information	<p>Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003</p>

EUROPEAN PATENT OFFICE

Patent Abstracts of Japan

PUBLICATION NUMBER : 2006089403
PUBLICATION DATE : 06-04-06

APPLICATION DATE : 22-09-04
APPLICATION NUMBER : 2004276179

APPLICANT : SENJU PHARMACEUT CO LTD;

INVENTOR : AKI HIROSHI;

INT.CL. : A61K 9/08 (2006.01), A61K 45/00 (2006.01), A61P 27/02 (2006.01), G02C 13/00 (2006.01)

TITLE : OPHTHALMIC COMPOSITION FOR TAKING OUT CONTACT LENS

ABSTRACT : PROBLEM TO BE SOLVED: To obtain an ophthalmic composition for enabling a contact lens to be easily taken out without adding excessive force and without using tools such as a sucker and a dropping pipet even if the contact lens adheres to the eye.

SOLUTION: This ophthalmic composition for taking out the contact lens is an aqueous composition having 0.01-0.12 or 0.29-0.56 ion strength, and preferably further contains at least one kind of medicinal component selected from a cornea-protecting agent, vitamins and amino acids.

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EUROPEAN PATENT OFFICE

Patent Abstracts of Japan

PUBLICATION NUMBER : 08152584
PUBLICATION DATE : 11-06-96

APPLICATION DATE : 30-11-94
APPLICATION NUMBER : 06296077

APPLICANT : ASAHI CHEM IND CO LTD;

INVENTOR : IKETANI TOMOJI;

INT.CL. : G02C 13/00

TITLE : CARE ARTICLE

ABSTRACT : PURPOSE: To improve fitting feeling of contact lens by dipping a contact lens in a soln. prepared by compounding one or more compds. selected from among pyrioxine hydrochloride, cyanocobalamin, etc.

CONSTITUTION: A soln. is prepared by compounding one or more compds. selected from among pyridoxine hydrochloride, cyanocobalamin, flavine adenine dinucleotide sodium(FAD). It is preferable to control the compounding amt. of these compds. to obtain 0.001-10% concn. in the soln. when a contact lens is dipped. If the amt. of these compd. is less than 0.0001%, the desired effect is hardly obtd. If the amt. exceeds 10%, an increase in the effect is not obtd. By this method, fitting feeling of a contactlens can be improved.

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